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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,960	01/30/2004	Evan Gustow	029318-0999	2511

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,960	GUSTOW ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 24, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,24-27,29-33,35,36,39-56,58,65,77-90,92 and 93* is/are rejected.

7)☒ Claim(s) *18-23,28,34,37,38,58,66-76,91 and 94-107* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-107 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on January 17, 2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. The objection to the specification for containing a hyperlink and/or other form of browser-executable code is hereby withdrawn as applicant, removed the hyperlink and/or other form of browser-executable code from the specification.

3. The objection to claims 12, 54 and 58 for containing trademarks is hereby withdrawn as applicant, removed the trademarks from the claims.

4. The rejection of claims 39-64 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn.

5. The rejection of claims 1, 2, 4, 6-8, 10 and 11 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7, 9-14 and 18-20 of U.S. Patent No. 6,592,903 in view of U.S. Patent No. 6,696,091 is being maintained for the reason stated in the previous office action.

6. The provisional rejection of claims 1-17, 24-27, 29-33, 35, 36, 39-46, 49-56, 58, 65, 77-90 and 92 on the grounds of nonstatutory obviousness-type double patenting as

being unpatentable over claims 1, 10, 11, 14, 16, 17, 19, 21-26, 28, 29, 32-38, 41, 46-50, 59, 60, 62, 63, 65, 67-70, 76, 77, 89, 90, 93, 95, 96, 98, 100-104 and 107 of copending application no. 10/619,539 in view of US Patent No. 6,696,091 is being maintained for the reason stated in the previous office action.

7. The rejection of claims 1, 2, 4, 6-8, 10 and 11 under 35 U.S.C. 103(a) over U.S. Patent No. 6,592,903 is hereby withdrawn.

8. The rejection of claims 1-17, 24-27, 29-33, 35, 36, 39-46, 49-56, 58, 65, 77-90 and 92 under 35 U.S.C. 103(a) over copending application no. 10/619,539 is hereby withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 2, 4, 6-8, 10 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7, 9-14 and 18-20 of U.S. Patent No. 6,592,903 in view of US Patent No. 6,696,091. The applicant and Patent '903 are directed to nanoparticle composition comprising an active agent and a surface stabilizer, wherein the nanoparticles have a particles size of less than 2 microns. The difference between the two is the active agent. The instant invention discloses the active agent as topiramate, whereas, the patent '903 discloses the active agent as a poorly soluble active agent. Claim 14 of '903 teaches classes of these poorly soluble active agents of which anti-epileptics are disclosed. US Patent 6,696,091 is be relied upon to teach that topiramate can be used to treat epilepsy (col. 2, lines 17-20). Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of '091, that topiramate can be used treat epilepsy in the invention of '903, which teaches the use of anti-epileptics drugs in nanoparticle compositions.

Response to Arguments

10. Applicant's arguments filed January 17, 2007 have been fully considered but they are not persuasive.

Applicant argues that there is no motivation to combine to obtained the claimed invention. Applicants argue that the "anti-epileptic compounds" of '903 encompasses a wide variety of subclasses and that one of ordinary skill in the art would not have any reasonable expectation of success in combining the two references. The examiner disagrees. Although antiepileptic compounds encompass a wide number of drugs, the

language of claim 14 of '903 is broad enough to encompass any and all compounds of that category, including topiramate as disclosed in '091.

11. Claims 1-17, 24-27, 29-33, 35, 36, 39-56, 58, 65, 77-90 and 92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 14, 16, 17, 19, 21-26, 28, 29, 32-38, 41, 46-50, 59, 60, 62, 63, 65, 67-70, 76, 77, 89, 90, 93, 95, 96, 98, 100-104 and 107 of copending Application No. 10/619,539 in view of US Patent No. 6,696,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed towards a composition comprising an active agent having a particles size of less than 2000 nm and at least one surface stabilizer. The difference between the two is the selection of the active agent and the addition of an osmotically active crystal growth inhibitor in '539. Claim 29 teaches that anti-epileptics can be used as an active agent. US Patent 6,696,091 is be relied upon to teach that topiramate can be used to treat epilepsy (col. 2, lines 17-20). Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of '091, that topiramate can be used treat epilepsy in the invention of '539, which teaches the use of anti-epileptics drugs in nanoparticle compositions. With respect to the addition of an osmotically active crystal growth inhibitor, the composition of the instant application is not limited to what is being claimed. The open language of comprising allows additional ingredients to be present. Furthermore, the osmotically active crystal growth

inhibitors as claimed such as glycerol, can be used as a surface-active agent (see claim 17 of '405).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Applicant's arguments filed January 17, 2007 have been fully considered but they are not persuasive.

Applicant argues that there is no motivation to combine to obtained the claimed invention. Applicants argue that the "anti-epileptic compounds" of '539 encompasses a wide variety of subclasses and that one of ordinary skill in the art would not have any reasonable expectation of success in combining the two references. The examiner disagrees. Although antiepileptic compounds encompass a wide number of drugs, the language of claim 29 of '539 is broad enough to encompass any and all compounds of that category, including topiramate as disclosed in '091.

Newly added claims 93-107

13. Claim 93 is being rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7, 9-14 and 18-20 of U.S. Patent No. 6,592,903 in view of US Patent No. 6,696,091. See above for statement of rejection.

14. Claims 94-107 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

the base claim and any intervening claims. The prior art does not teach the surface modifier as a surfactant.

Conclusion

15. Claims 1-17, 24-27, 29-33, 35, 36, 39-56, 58, 65, 77-90, 92 and 93 are rejected.

16. Claims 18-23, 28, 34, 37, 38, 57, 66-76, 91 and 94-107 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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